

**510(k) Summary
for
XiScan 6000 Imaging System**

1. SPONSOR

XiTec, Inc.
4 New Park Road
East Windsor, CT 06088

Contact Person: Steven Hanright
Telephone: (860) 627-7500

Date Prepared: November 17, 2000

2. DEVICE NAME

Proprietary Name: XiScan 6000 Imaging System
Common/Usual Name: Fluoroscopic mini C-arm systems
Classification Name: Image-intensified fluoroscopic X-ray system

3. PREDICATE DEVICES

XiScan Expert Imaging Systems (K984406)
Fluoroscanner Premier Mini C-arm System (K974058)
OEC Mini 6600 Digital Mobile C-arm System (K951765)

4. INTENDED USE

The XiScan 6000 Imaging System is intended for fluoroscopic imaging of patient extremities.

5. DEVICE DESCRIPTION

The XiScan 6000 Imaging System is a compact, mobile, mini C-arm system specifically designed for fluoroscopic imaging of patient extremities. The XiScan 6000 Imaging System can be operated in either manual or automatic exposure rate control (AERC) modes, with options of reduced radiation LOW DOSE and high resolution STANDARD DOSE when using AERC. The XiScan 6000 offers a range

of functions for image manipulations. It features touchscreen controls to manage on-screen patient information and image storage.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The XiScan 6000 Imaging System has the same intended use, and similar technical specifications, as compared to the predicate devices. All devices are mobile mini C-arm systems with similar technique factors, SIDs, field-of-view sizes, and image enhancement options. A bench test comparison of the devices confirmed that the patient X-ray exposure rates for imaging various anatomies are similar. Based on these comparisons, the XiScan 6000 Imaging System is substantially equivalent to the XiScan Expert Imaging Systems, Fluoroscan Premier Mini C-arm System, and OEC Mini 6600 Digital Mobile C-arm System.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 27 2000

XITEC, Inc.
c/o Sheila M. Hemeon-Heyer, Esq., RAC
Senior Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

Re: K003568
XiScan 6000 Imaging System
Dated: November 17, 2000
Received: November 20, 2000
Regulatory class: II
21 CFR 892.1650/Procode: 90 JAA
21 CFR 892.17.20/Procode: 90 IZL

Dear Ms. Hemeon-Heyer:

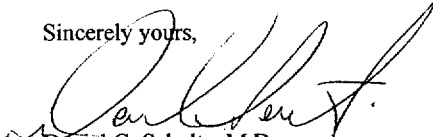
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,


Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known):

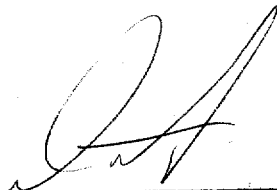
Device Name: XiScan 6000 Imaging System

Indications For Use:

The XiScan 6000 Imaging System is intended for fluoroscopic imaging of patient extremities.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K003568

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)